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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,320	11/26/2001	Teodulo Aves	06570/002002	1358

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EXAMINER

LAM, ANN Y

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 01/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/994,320

Applicant(s)

A

Examiner

Ann Y. Lam

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16 is/are allowed.
- 6) ☒ Claim(s) 1-15, 17 and 19-21 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-6, 8, 9, 11-15 are rejected under 35 U.S.C. 102(be) as being anticipated by Sardelis et al., 5,730,732.

Sardelis et al. discloses a needle (5) having a shaft (60) having a lumen extending from the proximal end of the needle shaft and terminating at an opening (80) on the top of the distal end of the needle shaft, wherein the cutting surface (90) is on the bottom of the hollow shaft of the needle.

As to claim 2, the cutting surface (90) is from the bottom of the distal end of the hollow shaft to the front of the distal end of the hollow shaft.

As to claim 3, the needle (5) is adapted to be used where the cutting surface is substantially parallel to the dural fibers.

As to claim 4, the sharpness of the cutting surface is considered to be, as measured by the grams of force required for the needle tip to puncture a sheet of two mil thick polyethylene, is from about 85 grams of force to about 100 grams of force, see for example, column 5, lines 5-13.

As to claims 5, 6, 11, 12, the needle is adapted to used in the procedures claimed.

As to claim 9, the cutting surface (90) begins on the bottom of the distal end of the hollow shaft and ends on the front of the distal end of the hollow shaft.

As to claim 13, a beveled surface is disclosed at (90), wherein the beveled surface is rounded and extends from the distal end of the cutting surface on the bottom of the shaft to the opening of the lumen on the top of the shaft.

As to claim 14, the beveled surface has a radial length less than about 25% of the needle outside diameter.

As to claim 15, the cutting surface (90) has the shape of a hull and extends from the outer edge of the bottom of the needle shaft to the front of the distal end of the shaft.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sardelis et al., 5,730,732.

Sardelis et al. discloses the invention substantially as claimed, see above, except for the needle being about 12 gauge to about 16 gauge. Sardelis et al. however teaches that the disclosed device can be used in various surgical procedures, see column 5, lines 19-20, and lines 52-65. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the Sardelis et al.

Art Unit: 3763

device in the dimensions as claimed, as necessary to perform surgery in a particular body cavity or joint.

4. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sardelis et al. 5,730,732, in view of Takai et al. 4,945,895. Sardelis et al. discloses the invention substantially as claimed, see above, except for a camera inside the lumen of the needle.

Takai et al. discloses a fiber optic (30) inside a needle for visualization during surgery. The fiber optic is equivalent to a camera as claimed. It would have been obvious to provide the fiber optic in the lumen of the Sardelis needle for visualization during various surgery as taught by Sardelis.

5. Claims 10, 17, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sardelis et al., 5,730,732, in view of Sharkey et al., 6,095,149.

Sardelis et al. discloses the invention substantially as claimed, see above, except for a solid rod and gripping means as claimed by Applicant.

Sharkey et al. discloses a needle and a solid rod (i.e., the disclosed obturator) having opposed proximal and distal ends, the distance between the opposed ends of the solid rod being substantially the same as the distance between the proximal end of an adapter attached to the needle and the distal tip of the needle shaft, the proximal end of the solid rod being secured to a gripping means (i.e., proximal end of the disclosed obturator) for holding the rod, the rod being insertable through the proximal end of the

Art Unit: 3763

adapter such that when the gripping means abuts the proximal end of the adapter, the distal end of the rod extends within the opening in the needle shaft, wherein the rod is adapted to prevent tissue debris from clogging the lumen during introduction of the needle into a patient's body, see column 8, lines 46-49.

Thus, it would have been obvious to provide an obturator as taught by Sharkey et al. in the Sardelis et al. needle in order to prevent tissue debris from clogging the lumen during introduction of the needle into a patient's body, as taught by Sharkey et al..

Allowable Subject Matter

Claim 16 is allowed.

Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703)308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

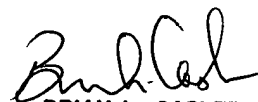
Application/Control Number: 09/994,320

Page 6

Art Unit: 3763

A.L.

January 27, 2003



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